REMARKS

The present amendment is fully responsive to the Office Action having a mailing date of December 2, 2010. Claims 2-3, 5-7, 9-14, and 20 have been amended. Claims 1, 8 and 25 have been canceled. Claims 27-30 were previously canceled. Claims 31-33 have been added. Thus, claims 2-7, 9-24, 26 and 31-33 remain pending. No new matter has been added by this amendment, and support for the claims as rewritten may be found throughout the specification and drawings. As Applicants' remarks with respect to the Examiner's rejections are sufficient to overcome these rejections, Applicants' silence as to assertions by the Examiner in the Office Action or certain requirements that may be applicable to such rejections (e.g., whether a reference constitutes prior art, motivation to combine references, assertions as to dependent claims, etc.) is not a concession by Applicants that such assertions are accurate or such requirements have been met, and Applicants reserve the right to analyze and dispute such assertions/requirements in the future. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03. Applicants respectfully request reconsideration of the present application in view of the following remarks.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 3-4, 8-9, 14, 16-18 and 22 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Buzzard et al. (U.S. 6,162,187) in view of Siegmund (U.S. 4,598,698). Claims 2 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Buzzard in view of Siegmund and in further view of Clement (U.S. 5,505,210). Claims 5, 7, 12, 18, 20, and 25 were rejected under 35. U.S.C. §103 (a) over Buzzard, in view of Siegmund and in further view of Miller (U.S. 2002/0082519). Claims 6, 10, 19 and 23 were rejected under 35 U.S.C.§103(a) over Buzzard in view of Siegmund and in further view of Moore (U.S. 2,866,457). Claims 11, 13, 24 and 26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Buzzard in view of Siegmund and in further view of Turturro (U.S. 6,331,165). For the reasons set forth below, Applicants respectfully traverse the rejections.

I. The Law

"To establish prima facie obviousness of a claimed invention, all the claim recitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). M.P.E.P. § 2143.03. Accord. M.P.E.P. § 706.02(j). Because all of the claim limitations are not taught or suggested by the various prior art combinations, the pending claims are patentable over the cited art.

II. Claims 1, 3-4, 8-9, 14, 16-18, 21 and 22

A. Independent Claim 1 and Dependent Claim 8

Independent claim 1 and dependent claim 8 have been canceled without waiver or disclaimer. Accordingly the rejection is moot with respect to claims 1 and 8.

B. Independent Claim 31

Independent claim 31 has been presented and claims 3-4 and claim 9 have been amended to depend therefrom. Independent claim 31 recites a biopsy system comprising a vacuum assisted biopsy device, a first fluid source, a second fluid source, and a fluid connector. The vacuum assisted biopsy device comprises an outer cannula and an inner cannula, wherein the inner cannula is configured for a reciprocating cutting stroke. A vacuum source is connected to the inner cannula to deliver vacuum through the inner cannula.

The fluid connector is positioned remotely from the biopsy device and comprises a body member defined by a first channel and a second channel, the second channel being integrally attached to the first channel such that the second channel intersects with the first channel. The first channel is defined by a first inlet port and an outlet port, the first inlet port is operatively connected to the first fluid source and the outlet port is operatively connected to the biopsy device.

The first channel further includes a first check valve connected thereto that is positioned distally of the first inlet port. The first check valve is in fluid communication with the first inlet

port. The second channel is defined by a second inlet port and a distal end, wherein the second inlet port is operatively connected to the second fluid source, and the distal end of the second channel opens into the first channel, proximal of the outlet port. The second channel further includes a second check valve connected thereto. The second check valve is positioned distally of the second inlet port such that the second check valve is in fluid communication with the second inlet port.

The biopsy system is configured to deliver vacuum from the vacuum source through the inner cannula to the fluid connector. The vacuum is configured to overcome a predetermined cracking pressure of the first check valve to automatically open the first check valve so as to automatically draw a predetermined amount of fluid from the first fluid source and deliver the fluid from the first fluid source into the outer cannula. The vacuum delivered through the inner cannula is configured to automatically open the second check valve to automatically draw a predetermined amount of fluid from the second fluid source and deliver the fluid from the second fluid source into the inner cannula.

Support for claim 31 may be found in at least claim 1, as previously presented, paragraphs [0028]-[0031]; [0040]; and [0043]-[0044], as well as FIGS. 1 and 1A, as originally filed. For example, paragraph [0043] recites "During each stroke of the inner cannula 36, the vacuum used to draw the biopsy sample through the inner cannula 36 will also draw a predetermined amount of fluid from fluid source 24 . . . Particularly, the aspiration pressure or vacuum will overcome the cracking pressure of first check valve 62, allowing a predetermined amount of fluid to be drawn into outer cannula 30 during each stroke." And paragraph [0044] recites "If second fluid source 65 is connected to second check valve 64, valve member 82 will be compressed such that the aspiration pressure or vacuum will automatically draw a predetermined amount of fluid, . . . from second fluid source 65 with every stroke of inner cannula 36."

C. Buzzard in combination with Siegmund Fails to Obviate Claim 31

Contrary to independent claim 31, Buzzard, alone or in combination with Seigmund, fails to teach, suggest or disclose two separate first and second fluid sources that are connected to a fluid connector. Nor do Buzzard and/or Seigmund disclose the structural components of the claimed

fluid connector, or that the fluid connector is configured to automatically permit fluid from the separate fluid sources to be *drawn into* the biopsy device via a separate vacuum source that delivers vacuum *through the biopsy device.* Accordingly, claim 31 is patentable over the cited combination.

Contrary to the assertions made in the Office Action, Buzzard does not disclose a first fluid source and a second fluid source as defined by claim 31. In the Office Action, reference was generally made to two full columns (Col. 6, line 13- Col. 8, line 12) and four figures as allegedly disclosing these features. A review of the text of these columns, as well as the figures themselves reveals just the opposite.

Indeed, as an initial matter, Buzzard is not directed to a biopsy system that is configured for *delivering* fluid to a biopsy device from two separate fluid sources. Instead, Buzzard teaches "a fluid *collection* apparatus for providing fluid communication *between* a vacuum source and *first and second vacuum lines* of a surgical device. The fluid collection apparatus comprises first and second fluid lines adapted for detachably connecting to, and in fluid communication with, the *first and second vacuum lines*, respectively, of the surgical device." *Abstract* (emphasis added).

Consistent with the Abstract, the text passages referenced in the Office Action make clear that first distal line 77 and the first fluid line 79 are connected to the handpiece 20 by first vacuum line 30: "First vacuum line 30 of handpiece 20 shown in FIG. 2 is fluidly connected to first valve 87 via a first fluid line 79, shown in FIG. 4." Col. 7, lines 52-54. Similarly, the second distal line 78 and the second fluid line 80 are connected to the handpiece 20 by second vacuum line 32: "Second vacuum line 32 of biopsy device 5 shown in FIG. 2 is fluidly connected to second valve 89 via second fluid line 80 shown in FIG. 4." Col. 7, lines 59-62. As seen clearly in FIGS. 2 and 4, reproduced below, there is simply no separate "first fluid source" and "second fluid source" in Buzzard. Instead, Buzzard teaches two separate *vacuum lines* for *collecting* fluids. *See, e.g.,* "Fluid collection system 60" in FIG. 2.

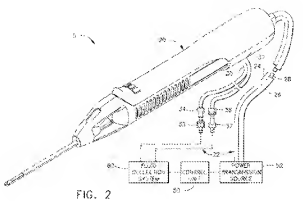


FIG. 2

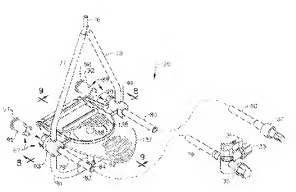


FIG. 4

Further, the distal lines 77 and 78 are connected together via a separate Y-connector 76, which is also connected to a separate common distal line 75, shown below in FIG. 3. Col. 7, lines 33-35. The common distal line 75 is attached to a vacuum canister 62. Col. 6, line 67-Col. 7, line 2. A vacuum pump line 64 is connected to a vacuum source inside the control unit 5 and supplies vacuum to the vacuum canister. *See,* Col. 6, lines 34-36.

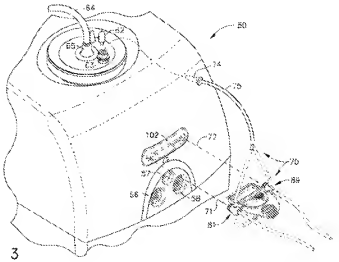


FIG. 3

Element 102, to which valves 81 and 89 connect to, is certainly not a fluid source, but rather a valve receptacle that is connected to an actuator 100. Actuator 100 drives the first valve 81 and second valve 89, as dictated by the control unit 50. Further, Buzzard explicitly states that either vacuum or atmospheric pressure is supplied to each of the lines, 30 and 32, to handpiece 20. *See* Col. 8, lines 12-23. Accordingly, Buzzard fails to teach, suggest or disclose a biopsy system having

a fluid connector for *delivering fluid* from two separate fluid sources to a biopsy device. To the contrary, Buzzard teaches a valve assembly for *collecting* fluid *from* a biopsy device. Thus, Buzzard actually teaches away from claim 31.

Siegmund does not make up for the deficiencies of Buzzard. As an initial matter, and contrary to paragraph 7 in the Office Action, Siegmund is not directed to a "biopsy system," but rather to "a diagnostic *endoscope*." *Abstract.* Indeed, the sections referenced in the Office Action only disclose undefined "retrieval" devices that may be *used* with an endoscope. For example, the first referenced passage, Col. 1, lines 9-21, actually describes "a typical prior art scope" that has a "retrieval mechanism." There is no description of the retrieval mechanism, including whether or not the "retrieval mechanism" is a vacuum assisted biopsy device. The second passage referenced in the Office Action actually makes clear that *no retrieval instrument is shown in the Siegmund reference:* It is noted that the scope includes an eyepiece 24, a channel entry 26 for a retrieval instrument *(not shown),* . . ." Col. 2, lines 41-42. Finally, the last reference cited in the Office Action again makes clear that a separate biopsy instrument, for which no details are provided is inserted into the endoscope described in Siegmund: Thus, the scopist's other hand is free to manipulate the syringe, or to insert a biopsy forcep into channel entry 26..." Col. 4, lines 1-4. Thus, there is no disclosure in Siegmund of a vacuum assisted biopsy device, as claimed in claim 31.

Further, Siegmund does not teach two separate fluid sources that are connected to a fluid connector positioned remotely from the biopsy device, whereby the fluid from the first fluid source is delivered *automatically* into the outer cannula of a biopsy device by vacuum that is delivered *through* the biopsy device, as set forth in claim 31. Nor does Siegmund teach *automatically* delivering fluid from the second fluid source into the inner cannula of the biopsy device by vacuum that is delivered *through* the biopsy device.

Instead, Siegmund teaches that a retrieval instrument is positioned within the channel entry 26 of the endoscope 18 and extends out of biopsy channel 45 of working end 15. *Manual compression* of the bulb 22 of endoscope 18 introduces air through conduit 20, through channel 40,

which is separate from biopsy channel 45, and thus separate from the undefined "retrieval instrument." *See* Col. 2, line 65-Col. 3, line 1. Further, while syringe 33 may be used to introduced fluid into the shaft 31, the syringe 33 must also be manually "pumped" so that fluid flows through conduit 25, blowing open check valve 32, until it discharges at face 15 through channel 40. Col. 3, lines 10-18. As the biopsy channel 45 is separate from the irrigation channel 40, Seigmund fails to teach, suggest or disclose a biopsy system having a remote fluid connector that is configured to *automatically* permit fluid from the separate fluid sources to be *drawn into* the biopsy device via a separate vacuum source that delivers vacuum *through the biopsy device* during operation of the biopsy device. Accordingly, claim 31 is patentably distinct from Buzzard and Seigmund.

D. Dependent Claim 3-4 and 9 are Patentable Over the Buzzard/Seigmund Combination

Claims 3-4 and 9 have been amended to depend from claim 31. While these claims contain additional subject matter that is independently patentable, these claims are also patentable over the Buzzard/Seigmund combination simply by virtue their dependency upon claim 31. Withdrawal of the rejection is therefore requested.

E. Buzzard in combination with Siegmund Fails to Obviate Claim 14

Independent claim 14 has been amended to recite a fluid connector for a biopsy system that includes a unitary body member defined by a first channel and a second channel. The second channel is integrally connected directly to the first channel. The first channel is defined by a first inlet port and an output port and the second channel is defined by a second inlet port and a distal end, whereby the distal end intersects the first channel proximally of the output port such that the second channel opens into the first channel. These features are not shown in the Buzzard/Siegmund combination. Support for these amendments may be found in at least paragraph [0033] and FIG. 2 as originally filed.

Buzzard does not disclose a "unitary body member" as claimed in claim 14. Indeed, as admitted in the Office Action, and as clearly shown below in FIG. 4, Buzzard discloses a series of separate fluid lines that serially connected together. For example, first distal line 77 is defined by two ends, a first one that is connected to valve member 93 and a second end that *receives* a separate Y-connector 76. Further, another, separate fluid line 76 has a first end connected to valve member

93, and a second end connected to a first female connector 35 which separately mates with a corresponding male connector 34 that is attached to a first vacuum line 30 extending from the handpiece 20. Second distal fluid line 78 is similarly arranged. For example, second distal fluid line 78 includes a first end connected to valve element 94 and a second end that is connected the separate Y-connector 76. A second fluid line 80 includes a first end connected to the valve element 94 and a second end connected to a second female connector 37 that separately mates with a corresponding mail connector 36 that is attached to a second vacuum line 32 extending from the handpiece 20. Accordingly, Buzzard fails to teach a *unitary* body member as claimed.

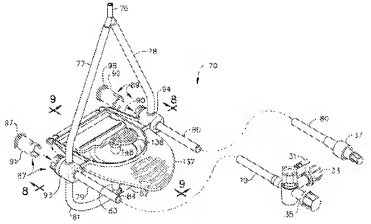


FIG. 4

Further, the second distal fluid line 78 in Buzzard does not intersect or open into the first distal fluid line 77. Nor does the end of the second distal fluid line 78 intersect proximally of an outlet outlet port of the first distal fluid line 77. Instead, *a separate Y-connector* 76 connects ends of the first and second fluid lines 77, 78.

Seigmund also fails to make up for the deficiencies of Buzzard. As previously explained in prior office actions, Seigmund is not directed to a fluid connector, but rather is an endoscope. While the endoscope 18 includes conduits 55 and 20, these conduits do not intersect one another. Accordingly, for at least these reasons, claim 14 is patentable over the cited art.

Claim 14 also requires that the first check valve and the second check valve are configured to automatically open when a vacuum is introduced through the biopsy device and to the fluid connector, so as to deliver fluid from the first and second fluid sources to the biopsy device. As

described above in connection with the discussion on claim 31, these limitations are also not shown in the prior art. Accordingly, claim 14 is also patentable over the Buzzard/Siegmund combination.

F. Dependent Claim 16-18 and 21-22 are Patentable Over the Buzzard/Seigmund Combination

Claims 16-18 and 21-22 have been amended to depend from claim 14. While these claims contain separately patentable subject matter, these claims are also patentable over the Buzzard/Seigmund combination simply by their dependency upon claim 14. Withdrawal of the rejection is therefore requested.

III. Claims 2 and 15

Claims 2 and 15 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Buzzard, et al. in view of Siegmund and in further view of Clement (U.S. Patent No. 5,505,210, hereinafter "Clement").

As an initial matter, claim 2 has been amended to depend from new claim 31. As noted above with regard to independent claim 31, the combination of Buzzard and Siegmund fails to teach, suggest or disclose two separate first and second fluid sources that are connected to a fluid connector that is positioned remotely from a biopsy device. Nor do Buzzard and/or Seigmund disclose the structural components of the claimed fluid connector, or that the fluid connector is configured to automatically permit fluid from the separate fluid sources to be *drawn into* the biopsy device via a separate vacuum source that delivers vacuum *through the biopsy device*. However, Clement does not make up for the deficiencies in the teachings of Buzzard and/or Siegmund. For example, nowhere does Clement disclose, teach or suggest a fluid connector that is positioned remotely from a biopsy device as claimed by Applicants. Indeed, Clement teaches an irrigation and suction lavage assembly that includes a moveable outer cannula with a cutter. The biopsy device includes a duckbill flap valve 740 *in the biopsy device*, not a separate fluid connector that is *remotely* positioned from the biopsy device.

Further, the duckbill flap valve 740 is not opened *automatically* in response to vacuum delivered through the biopsy device. Instead, the duckbill flap valve 740 is *manually* opened when a medical device 750 is passed through the valve 740. Col. 12, lines 22-37.

Therefore, as combination of references fail to discloses a fluid connector that is *remotely* positioned from a vacuum biopsy device as positively claimed by Applicants, and because the combination of references fail to teach valve elements that are automatically opened in response to vacuum delivered through the biopsy device and to the fluid connector, the combination of references fails to teach or suggest all of the elements of independent claim 31 and 14 under *In re Royka*. Accordingly, claim 2 which depends from independent claim 1 is patentable over the references for at least this reason. Moreover, dependent claim 2 contains additional recitations that are separately patentable as well. Accordingly, withdrawal of the rejection is respectfully requested with respect to claim 2.

Claim 15 is also patentable over the cited combination. Claim 15 depends from claim 14, which, as demonstrated above, is patentable over the Buzzard/Siegmund combination. Clement fails to make up for the deficiencies of the Buzzard/Siegmund combination with respect to claim 14. Accordingly, claim 15, which depends from claim 14, is also patentable over the references. Withdrawal of the rejection is therefore respectfully requested.

IV. Claims 5, 7, 12, 18, 20 and 25

Claims 5, 7, 12, 18, 20 and 25 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Buzzard, et al. in view of Siegmund and in further view of Miller et al. (U.S. Publication No. 2002/0082519, hereinafter "Miller"). Claim 25 has been canceled and therefore the rejection is moot with respect to claim 25.

Claims 5, 7, and 12 have all been amended to depend from independent claim 31 and claims 18 and 20 depend from claim 14. As noted above with regard to independent claims 31 and 14, neither Buzzard nor Siegmund disclose a fluid connector that comprises a body member defined by a first channel and a second channel, wherein the second channel intersects the first channel. Nor

does Buzzard and Siegmund disclose a fluid connector that is provided remotely from a vacuum assisted biopsy device.

However, Miller does not make up for the deficiencies in the teachings of the Buzzard/Siegmund combination. Nowhere does Miller disclose, teach or suggest a fluid connector wherein the first and second channels intersect one another that is positioned remotely from the biopsy device. Indeed, Miller teaches a biopsy device that a pinch valve 402 that is connected to a single fluid source 400. However, as stated in the background of the present application, which is describing the construction of the biopsy device disclosed in Miller, the pinch valve is used to crimp the fluid supply line to selectively interrupt the flow of saline solution to the surgical site. However, the fluid connector of the system claimed in claims 31 and 14 was designed to permit a second fluid to the biopsy device, without "breaking" the fluid supply of the biopsy device or separately requiring injection into the fluid supply line. See paragraph [0004]. Thus, Miller actually teaches away from the claimed biopsy system and fluid connector.

Further, Buzzard also teaches away from using pinch valve configurations. Buzzard expressly touted the valve arrangement disclosed therein as providing "numerous advantages over other types of valves such as, for example, pinch valves." Col. 7, lines 65-67. Indeed, Buzzard denigrates the use of pinch valves. *See also* Col. 8, lines 1-12. Accordingly, one of ordinary skill in the art would not choose to combine Buzzard with Miller.

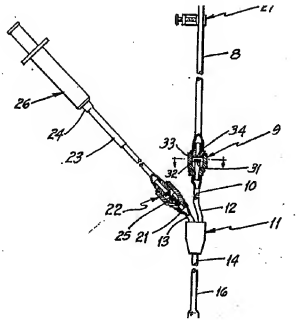
Therefore, as neither of the references discloses a separate fluid connector having the claimed features of independent claims 31 and 14, including one that is *remotely* positioned from the biopsy device as claimed by Applicants, the combination of references fails to teach or suggest all of the elements of independent claims 31 and 14 under *In re Royka*. Accordingly, claims 5, 7, 12, 18, and 20, which depend from independent claims 31 and 14 respectively, are patentable over the references for at least this reason.

V. Claims 6, 10, 19, and 23

Claims 6, 10, 19, and 23 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Buzzard et al. in view of Siegmund and in further view of Moore (U.S. Patent No. 2,866,457, hereinafter "Moore"). Applicants respectfully traverse the rejection.

As noted above with regard to independent claims 31 and 14, as set forth above, the Buzzard/Siegmund combination fails to disclose a fluid connector that comprises a body member defined by a first channel and a second channel, wherein the first channel intersects the second channel. Nor does Buzzard/Siegmund combination disclose a first check valve that is positioned *distally* of the first inlet port.

However, Moore does not make up for the deficiencies in the teachings of Siegmund. Indeed, Moore also fails to disclose a body member having first and second input ports, a first check valve positioned distally of the first input port as claimed by Applicants. More specifically, Moore is directed to an apparatus for administration of parenteral fluid; a portion of Figure 1 of Moore is reproduced below:



Moore discloses a connection 11, which includes a first inlet leg or inlet passage 12, a second inlet leg or passage 13, and an outlet leg or passage 14. Check valve 9 is connected by tubing 10 to

connection 11. Second leg 13 is connected by a short length of tubing 21 to a second check valve 22. See Col 1, line 61 – Col 2, line 1 and Fig. 1 of Moore.

The check valves of Moore are separated from connection 11 by tubing 10 and 21. Check valves 9 and 21 of Moore are connected to tubing 10 and 21 respectively, which are in turn connected to first leg 12 and second leg 13 respectively. Check valves 9 and 21 are spaced from connection 11 such that inlet ports of connection 11 must be positioned between connection 11 and check valves 9 and 21. Accordingly, as neither check valve of Moore is positioned *distally* of inlet ports of connection 11, Moore cannot make up for the deficiencies of the Buzzard/Siegmund combination.

Therefore, the combination of references fails to teach or suggest all of the elements of independent claims 31 and 14 under *In re Royka*. Accordingly, claims 6, 10, 19, and 23, which depend from independent claims 31 and 14 respectively, are patentable over the references for at least this reason. Moreover, dependent claims 6, 10, 19, and 23 each contain additional recitations that are separately patentable as well.

VI. Claims 11, 13, 24, and 26

Claims 11, 13, 24, and 26 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Buzzard, et al. in view of Siegmund and in further view of Turturro et al. (U.S. Patent No. 6,331,165, hereinafter "Turturro"). Applicants respectfully traverse the rejection.

Turturro does not make up for the deficiencies in the teachings of the Buzzard/Siegmund combination. Turturro is directed to a biopsy instrument having separate irrigation and aspiration passageways 620 and 622, respectively. As may be seen below in FIG. 28, passageways 620 and 622 are separate passageways that do not intersect one another. Further, each passageway includes a port, irrigation port 624 and aspiration port 626. However, neither irrigation passageway 620, nor aspiration passageway 622 include a check valve positioned *distally* of either the irrigation port 624 or the aspiration port 626. Accordingly, as Turturro fails to disclose a check valve positioned

distally of a first inlet port, Turturro cannot make up for the deficiencies of the Buzzard/Siegmund combination.

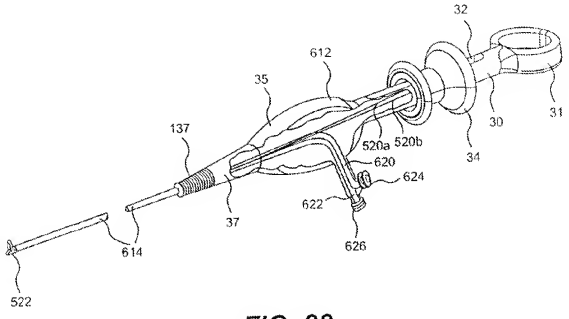


FIG. 28

Therefore, the combination of references fails to teach or suggest all of the elements of independent claims 31 and 14 under *In re Royka*. Thus, claims 11, 13, 24, and 26, which depend from independent claims 31 and 14 respectively, are patentable over the references for at least this reason. Withdrawal of the rejection is therefore respectfully requested.

VII. New Claims 32-33

New claims 32-33 have been presented herein. New claims 32-33 are both dependent upon claim 31 and therefore are patentable over the cited art by virtue of that dependency. Support for these claims may be found in at least paragraph [0032] and FIG. 1, as originally filed.

Conclusion

In view of the above amendment and remarks, the pending application is in condition for allowance. If, however, there are any outstanding issues that can be resolved by telephone conference, the Examiner is earnestly encouraged to telephone the undersigned representative.

Any fees due with this response are identified in an accompanying transmittal. However, if any additional fees are due, please charge our Deposit Account No. 18-0013, under Order No. 65937-0045 from which the undersigned is authorized to draw. To the extent necessary, a petition for extension of time under 37 C.F.R. §1.136 is hereby made, the fee for which should also be charged to this Deposit Account.

Dated: April 4, 2011
(the 2nd falling on a Saturday)

Respectfully submitted,

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